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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEUBECKER, JOHN P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/660,840	Applicant(s) REMIJAN ET AL.	
	Examiner John P. Leubecker	Art Unit 3779	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-18,22-33,35,39,51,59-69 and 81-90 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1-18,22-33,35,39,81,82 and 84-90 is/are allowed.
- 7) ☒ Claim(s) 51,59-69 and 83 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 59 and 83 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 59, recitation that the illumination waveguide has a thickness in a range of 0.1 mm to 0.2 mm is redundant since such limitation is now set forth in claim 51.

As to claim 83, this claim does not depend on a preceding claim.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 51, 59-61 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302), Kurtzer (U.S. Pat. 5,168,863) and Santangelo et al. (U.S. Pat. 4,610,242), and further in view of Ohshiro (U.S. Pat. 4,569,334).

As to claim 51, Siegmund et al. discloses a rigid probe including an optical waveguide (1), a concentric fiberoptic illumination channel (25, col.4, lines 26-28), a handle (3,27) removably attached (via threads 39, such coupling anticipating first and second coupling elements) to the probe, a light source (33) that is optically coupled to the illumination channel

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within the handle via a fiber optic reducer (29), an optical lens element (5, which can be a positive lens, negative lens or lens system (col.4, lines 9-10), such lens system would encompass a first and second lens; in addition note Figs. 8a-8c and 9) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay.

Siegmund et al. fails to specify the length and diameter of optical waveguide. However, analogous miniature endoscopes (note Allred, III, Figure 2, col. 4, lines 28-34) are known to include an optical waveguide with a diameter of 2 mm or less and a length of somewhere between 3.3 cm and 11 cm¹. Since Siegmund et al. fails to teach any particular length and diameter, it would have been obvious to one of ordinary skill in the art to have made the waveguide any desired diameter and length to meet the particular requirements for a certain procedure, and specifically, any length and diameter contemplated in the prior art, since such contemplation suggests a particular need or use for those dimensions in the prior art. Clearly a diameter of less than 2 mm, as taught by Allred, III would encompass the diameters 0.6 mm to 1.6 mm.

Siegmund et al. further fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which

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are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

Siegmund et al. discloses the endoscope as claimed but further fails to disclose a separate cannula that receives the distal end of the probe such that the outer sheath (37) slides within the cannula and that the cannula has a locking mechanism at a proximal end that attaches to the probe. Santangelo et al. demonstrates what is conventional in the endoscope art in that endoscopes are known to be used with a cannula and trocar (stylet) for providing an entry site for the endoscope into the body through the skin (col.1, lines 14-35). Santangelo et al. teaches such cannula/trocar combination (Figs.2,3) wherein the cannula (18,20, Fig.1) includes a locking mechanism (30 in Fig.1 or 31'/36' in Fig.11) at a proximal end to attach to a hub (22) of the endoscope. In addition, Santangelo et al. further teaches a fluid delivery port (51,col.4, lines 62-64) on the cannula for introducing or aspirating fluid through the cannula. It would have been obvious to one of ordinary skill in the endoscope art to have used the endoscope of Siegmund et al. with the cannula/trocar arrangement of Santangelo et al., if not for the fact that such combination of devices are known and used, for the purpose of providing an entry site into the patient (col.1, lines 29-30), protecting the distal end of the endoscope (col.1, lines 41-45) and allowing quick and easily insertion of the endoscope to a proper axial and rotational position (col.1, line 69 to col.2, line 6).

Siegmund et al., as described above, further fails to disclose the thickness of the illumination waveguide. The thickness of such (e.g., distance between sheath 53 and image guide 1 in Figure 6a) depends on the diameters of the optical fibers making up the waveguide.

¹ The probe sleeve (18) is about 3.3 cm in length and the main housing (12) about 7.5 cm in length. Since the

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Optical fibers can have a diameter of at least one millimeter to as small as 10 micrometers.

Ohshiro teaches that illumination waveguides can comprise multiple fibers each having a diameter as small as 10 micrometers. Given these dimensions, a thickness of illumination waveguide of Siegmund being 0.1 to 0.2 mm is contemplated in the art and would have been obvious to one of ordinary skill since known optical fiber diameters would encompass the claimed thickness.

As to claim 60, note ring of optical fibers (25) and optical lens element (5, which can be a positive lens, negative lens or lens system (col.4, lines 9-10), such lens system would encompass a first and second lens; in addition note Figs. 8a-8c and 9). As to claim 61, the light source is a lamp (col.4, lines 36-37). As to claims 63 and 64, note in Kurtzer that the sterile barrier (20) is attached to the probe via a disposable probe element (13, Fig.6, col.5, lines 37-59). As to claim 65, note locking mechanism (30) mentioned above with respect to Santangelo et al. As to claim 66, probe would fit within the cannula as noted above with respect to Santangelo et al. As to claim 67, note col.6, lines 17-26 regarding a locking mechanism (70) and further note the locking mechanism of Santangelo et al. As to claim 68, the cannula tip (21) forms a needle (note tapered pointed end 21, Fig.1 of Santangelo). As to claim 69, the trocar (60, Fig.3) constitutes a stylet.

5. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302), Kurtzer (U.S. Pat. 5,168,863), and Santangelo et al. (U.S. Pat. 4,610,242) and Ohshiro (U.S. Pat. 4,569,334), as described above and further in view of Koeda et al. (U.S. Pat. 5,746,494).

optical waveguide (24) extends slightly into the main housing (note proximal end 42, Fig.2), it would have a length

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Siegmund et al., as described above, fails to disclose the particulars of the connection between the light source (33) and the illumination waveguide . Koeda et al. is just one of numerous examples of the level of ordinary skill in the art regarding the coupling of a light source with an optical fiber. Koeda et al. teaches use of a lens (111c or 114, Fig.4) for coupling light from a lamp to a fiber optic bundle to provide a efficient coupling while maintaining good luminous intensity distribution characteristics (col.2, lines 10-15). It would have been obvious to have provided a lens for coupling light from a light source to an optical fiber for the desirable reasons set forth above.

Allowable Subject Matter

6. Claims 1-18, 22-33, 35, 39, 81, 82 and 84-90 are allowed.
7. Claim 83 would be allowable if amended to depend directly or indirectly from claim 1. Claim 83 would be rejected for the reasons set forth above (length and diameter dimensions set forth above anticipates the claimed ratio) if amended to depend directly or indirectly from claim 51.

Response to Arguments

8. Applicant's arguments filed September 22, 2011 have been fully considered but they are not persuasive.

Regarding the Siegmund reference, Applicant continues to argue that one skilled in the art would not be motivated to provide the Siegmund device at the claimed size (diameter less

of somewhere between 3.3cm and the overall length of about 11 cm.

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than 2 mm and imaging channel in range of 0.6 mm to 1.6 mm) in view of the resulting loss in image size and resolution, thus compromising diagnostic value. Besides lacking any evidence to support such degradation in image quality, this argument raises the question as to how Applicant's alleged invention allows an optical system of the claimed size without loss in image size and resolution. Such structural features are not disclosed and certainly not claimed in claim 51. In any event, the Examiner has provided evidence that imaging probes of the claimed size have been contemplated in this art. There is no suggestion in these references or any evidence provided by Applicant that the claimed size would provide any problems with imaging.

Applicant also argues that Siegmund "employs a large illumination area". It appears that Applicant is basing such allegation on the Figures of Siegmund which are not disclosed as being to scale. The fact of the matter is, Siegmund does not disclose any particular size for the thickness of the illumination channel. The Examiner maintains the position that one of ordinary skill in this art, when reducing the Siegmund device to practice, must turn to the prior art for information concerning the size of the optical fibers in the illumination channel. Known sizes would make obvious the claimed thickness.

With respect to the Allred reference, Applicant argues that Allred does not teach "a disposable component" or the "mounting hub structure" of the probe. Although these elements are not in claim 51, it is noted that the Examiner does not purport that Allred teaches such elements. In fact, Allred is only relied on to teach the claimed sizes for the probe and imaging channel. Applicant does not address Allred with respect to the claimed sizes.

It is noted that the rejections appearing above are substantially identical to those in the previous Office Action. Note that since Applicant imported a limitation from claim 59 into

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claim 51, the Ohshiro reference is now included in the rejection, as per the rejection of claim 59 in the previous Office Action.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571)272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
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jpl